Core outcome sets

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Published in:
BJOG-an International Journal Of Obstetrics And Gynaecology

DOI:
10.1111/1471-0528.15336

Publication date:
2019

BJOG An International Journal of Obstetrics and Gynaecology

Core outcome sets: a barrier-free tool for research?

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Linked article: This is a mini commentary on S Meher et al., pp. 83–93 in this issue. To view this article visit https://doi.org/10.1111/1471-0528.15335

Published Online 28 July 2018.

The paper by Meher et al. introduces two well-defined core outcome sets (COS) for postpartum haemorrhage (PPH), one for prevention and one for treatment.

Since the launch of the COMET initiative in 2010, a growing number of COS have been developed, and a substantial additional number are registered on the COMET website (www.comet-initiative.org). In the field of Obstetrics and Gynaecology, a group of Journal editors initiated the CROWN initiative (www.crown-initiative.org) to highlight the need to adhere to COS: researchers should report all elements of an existing COS for trials on a topic or indicate valid reasons why they did not, in order for their manuscript to be considered for publication in these Journals.

Core outcome sets are developed with the idea to reduce waste in research by selecting those outcomes that are relevant and applicable in most research settings. They enforce that not only positive significant findings are reported, but also relevant nonsignificant or negative findings.

Do COS present another barrier to research by forcing researchers to abandon their preferred study design? We do not think so: they explicitly *do not* imply that outcomes should be restricted to those in the core set. Rather, individual studies can report any study-specific outcomes in addition. Their use facilitates focused and relevant research by optimising comparability of data and pooled data synthesis like individual patient data meta-analysis, the highest level of evidence.

Although COS are driving forward the field of data synthesis, their use is not the only requirement for optimal comparability of studies. Standardisation of 'how' to measure these outcomes, that is which measurement instrument to use, is also vital. For example: when considering blood loss as one of the outcomes of the PPH COS: how should it be measured? By estimation of blood loss or by weighing? How to weigh (with what tool?) and correct for amniotic fluid or urine?

Finally, for optimal comparability of studies, reporting baseline characteristics (usually mentioned in the first table of an article) should be standardised. For example: what should be reported on study population characteristics regarding health, age, socio-economic status, smoking status and alcohol intake, selected versus unselected population, etc. Therefore, the use of a minimum reporting set – alongside a COS – with measurement instruments would further facilitate comparison and data synthesis.

Core outcome sets (and their measurement instruments) are developed through a well-described consensus procedure, by tapping into the common contemporary knowledge of individual participating experts, including lay experts/patient representatives. [*The COMET Handbook* version 1.0, Williams et al. 2017 *Trials* 18 (Suppl 3): 280 https://doi.org/10.1186/s13063-017-1978-4]. It must be remembered that these consensus procedures bear an inherent source of bias, related to participants and time (as new evidence may develop). It is important to carefully balance participants between stakeholder groups in order to weigh in minority opinions and prevent attrition bias (thereby overestimating agreement).

Consensus procedures to define minimum items to report in studies optimise interpretation and data synthesis of different studies in the same research subject. They are not 'the truth', and their interpretation requires an overarching perspective of their limitations in order to appreciate their virtues.

Disclosure of interests

Full disclosure of interests available to view online as supporting information. ■